

## REMARKS

### I. Status of the Application

Claims 1-56 are pending in this application. Claims 24, 36 and 52 are cancelled, and new claims 57-72 are added. Claims 16-26 stand rejected under 35 U.S.C. § 101 as being directed to non-statutory subject matter. Claims 1-3, 5, 10, 11, 13, 14, 34-36, 38, 43, 44, 46 and 47 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Yapp, 0 099 167. Claims 27, 28, 49 and 50 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Vincent et al., U.S. 5,007,935. Claims 51-56 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Masini, U.S. 5,571,203. Claims 4, 5, 7-9, 12, 15, 37, 40-42, 45 and 48 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Yapp. Claims 6 and 39 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Yapp in view of Grimes, U.S. 4,795,473. Claims 29-33 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Masini in view of Tager et al., U.S. 5,330,536.

Applicant has amended certain of the claims and added new claims to more clearly define and distinctly characterize Applicant's novel invention. Claims 16-18 have been amended to clarify that the bone referred to therein is exogenous bone. Claim 21 has been amended to depend from claim 18, rather than 16, to provide claim 21 with proper antecedent basis. Claim 26 has been amended to remove the "preferably" clause. Support for the amendments and for the new claims can be found in the specification and the claims as originally filed. Support for the amendments to claims 34 and 51 can be found in the specification at least at page 7, lines 10-21 and in original claim 7. Support for new claims 57 and 58 can be found in the specification at least at page 9, lines 16-23 and in the figures, particularly Figures 1C and 3. Support for new claim 59 can be found in the specification at least at page 2, lines 24-30; page 8, lines 25-28; page 9, lines 28-30; Figures 1C and 8, and claim 12 as originally filed. Support for

claim 60 can be found at least at page 13, lines 1-3; page 16, lines 18-19; and Figure 8. Support for claim 61 can be found at least at Figure 1C. Support for claim 62 can be found at least at page 2, lines 24-30. Support for claims 63 and 72 can be found at least at Figure 8. Support for new claims 64-66 and 68-71 can be found at least at page 7, lines 10-21. Support for new claim 67 can be found at least as for new claim 59 and at page 1, lines 11-15; page 4, line 22 to page 5, line 9; and page 5, line 27 to page 6, lines 4.

New claim 57 is believed to be patentable over the references of record in this case because, with the exception of Masini, claim 51, from which new claim 57 depends, has not been rejected. The patentability of new claim 57 with respect to Masini, optionally in view of Tager et al., is addressed below. Applicant respectfully submits that the amendments and new claim presented herein add no new matter.

Applicant respectfully requests entry and consideration of the foregoing amendments, which are intended to place this case in condition for allowance.

## II. Claims 16-26 Are Directed to Statutory Subject Matter

Claims 16-26 stand rejected under 35 U.S.C. § 101 as being directed to non-statutory subject matter. Applicant respectfully traverses this rejection based on the claims as amended.

Applicant has already noted, in a previous response, that Applicant is not claiming the insertion of a fastening element into a human, but rather is claiming an ex vivo assembly of bone and a fastening element. Claim 16 is described at page 3, line 21 – page 5, line 13 of the specification. Exogenous bone can be mounted to a fastening element of the type described in the claims, wherein the exogenous bone has both cortical and spongy portions. The supporting element abuts against an abutment surface of the exogenous bone, which can be, for example,

created in the same fashion as would be created in a bone of a living human being. The claims have been amended to clarify that the bone of the claims is exogenous.

Such an assembly would be desirable in the case, for instance, where bone loss has occurred, for example, through physical trauma or as a result of radiation therapy. It is in this type of circumstance that bone ingrowth may occur, as bone ingrowth can occur from the living bone of the recipient into portions of the pin extending through the exogenous bone and into the living bone. Note that the specification states only that “[b]one ingrowth into and/or against the pin can then be promoted.” The specification does not require that the bone ingrowth come from the bone against which the supporting element abuts. Of importance, such bone ingrowth is not recited in any of claims 16-26 and should not be read into said claims by virtue of being included in the specification in an optional sense by virtue of the phrase “*can* then be promoted.” Other possible uses for such an assembly, which include the use of an exogenous bone/fastening element assembly as a teaching, instructional or training aid in teaching the appropriate technique to the surgeons who will install fastening elements or to aid in explaining the technique to potential recipients of a fastening element of the type utilized in the assembly of claims 16-26, clearly would not be amenable to such optional promotion of bone ingrowth.

As the Applicant is clearly not including within the scope of these claims a human being, Applicant respectfully requests that the rejection of claims 16-26 under U.S.C. § 101 be reconsidered and withdrawn.

### **III. The Claims Are Novel Over Yapp**

Claims 1-3, 5, 10, 11, 13, 14, 34-36, 38, 43, 44, 46 and 47 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Yapp, 0 099 167. Applicant respectfully traverses this rejection.

Yapp fails to disclose each and every element of the subject claims. Yapp fails to disclose a fastening element for an implant having an at least largely hollow pin having an inside bone contact surface and an outside bone contact surface as required by claim 1. The surfaces cited by the Examiner as corresponding to the inside and outside surfaces of the pin, namely bone contact surfaces 20 and 22, are instead the outside surface of the Yapp pin (20) and the surface of the supporting flange adjacent the transected surface of the bone (22) (see Figure 3 and page 6, line 7 of Yapp). It can clearly be seen that the pin of Yapp is not largely hollow and instead comprises a solid block with a porous surface and with a channel for receiving screw 28; see Figure 4 of Yapp. The specification of Yapp further makes this point clear at page 2, lines 25-27, which states “[t]he passageway is precisely cut to match the configuration of the shaft...” and at page 4, lines 28-30, stating “the passageway 14 is cut with a configuration matched to the shaft 13 so that the shaft will fit tightly therein.” Even were Yapp to have a largely hollow pin, any inside surface of the pin of Yapp would still not be a bone contact surface because the bone material that might fill such a pin is removed to make the passageway. Thus, Yapp does not anticipate claim 1 or claims 2-3, 5, 10, 11, 13, and 14, each of which depend from claim 1.

Yapp likewise fails to disclose a fastening element for an implant with a pin having a longitudinal axis extending at an angle of between about 125° and about 145° with respect to the bottom surface of the supporting element as required by claim 34. As can be seen in Figures 2, 4 and 7 of Yapp, the Yapp pin 13 extends at approximately a 90° angle from the bottom surface of flange 24, which ultimately requires far more bone material be removed than is required by the claimed fastening element. See also page 4, lines 23-25, which notes that the passageway portion 40 (in which the pin 13 resides) is generally perpendicular to the generally flat transected

surface 16 of the neck of the bone. Yapp therefore does not anticipate claim 34, or claims 36, 38, 43, 44, 46 and 47, which depend from claim 34.

New claim 58 is novel over Yapp because Yapp fails to anticipate claim 34, from which claim 58 depends.

Applicant respectfully submits that new claims 59-72 are also patentable over Yapp. Yapp fails to disclose a fastening element for hip prosthesis having a coupling element extending from a second side of the supporting element and offset with respect to the longitudinal axis of the pin as required by claims 59 and 67, from which each of the remaining claims depend. Instead, Yapp discloses a coupling element that is in line with the longitudinal axis of the Yapp pin (20). Thus, Yapp does not anticipate claims 59 or 67 or claims 60-66 and 68-72, which depend from claims 59 and 67. Yapp further does not disclose cementing the fastening element in place as required by claim 67. Yapp instead uses bolt 28 to secure the fastener.

Yapp likewise fails to disclose a fastening element for an implant with a pin having a longitudinal axis extending at an angle of between about 125° and about 145° with respect to the bottom surface of the supporting element as required by claim 64 and 69. Similarly, Yapp does not disclose a pin having a longitudinal axis extending at an angle greater than about 145° as required by claims 66 and 71. Such permits a much smaller portion of the bone to be removed, as the supporting element need not reside over the longitudinal axis of the bone. This angle corresponds to the neck angle of the original bone. See page 7, lines 10-21 of the present application. As can be seen in Figures 2, 4 and 7 of Yapp, the Yapp pin 13 extends at approximately a 90° angle from the bottom surface of flange 24, which ultimately requires far more bone material be removed than is required by the claimed fastening element. See also page 4, lines 23-25, which notes that the passageway portion 40 (in which the pin 13 resides) is

generally perpendicular to the generally flat transected surface 16 of the neck of the bone. For this separate and additional reason, claims 64, 66, 69 and 71 are novel over Yapp.

As Yapp does not disclose each and every limitation of claims 1-3, 5, 10, 11, 13, 14, 34-36, 38, 43, 44, 46, 47 and 58, Applicant requests that the rejection of those claims under 35 U.S.C. § 102(b) be withdrawn and that the claims be allowed over Yapp, and further that all new claims be allowed over Yapp.

#### **IV. The Claims Are Novel Over Vincent et al.**

Claims 27, 28, 49 and 50 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Vincent et al., U.S. 5,007,935. Applicant respectfully traverses this rejection.

Vincent et al. fail to disclose each and every element of claims 27, 28, 49 and 50. Vincent et al. does not disclose holes having a centerline extending parallel to the angle between a supporting element of the fastening element and the longitudinal axis of the pin as required by claims 27 and 49 (and 28 and 50, which depend from 27 and 49, respectively). Certain of the structures of Figure 3 of Vincent et al. referred to by the Examiner, namely 73, 87, and 83, are not described in the specification of Vincent et al., and reference number 82 is used to indicate two different structures in Figure 3, with the text clearly referring to the bore through which screw 89 extends and not the hole in structure 73. It would be clear to one of skill in the art, however, that the presumed screw holes 87, through which screws 85 extend, do not have a centerline extending parallel to the angle between a supporting element and the longitudinal axis of the pin. See, for example, Figure 2, which indicates that the screws 20 (which would correspond to screws 85) extend at an angle different from that of the pin; the bores through which the screw pass would likewise have a centerline extending at an angle not parallel to the

angle between the supporting element and the longitudinal axis of the pin (i.e. the centerlines are not parallel with the pin when the pin is inserted). Note that, in accordance with the requirement of claims 28 and 50 that the tool further comprise at least one central opening, the central opening 82 of structure 73 is not the hole which must meet the centerline extending at an angle not parallel to the angle between the supporting element and the longitudinal axis of the pin requirement.

Similarly, Vincent et al. fail to disclose a template having a hole pattern corresponding to the circumference of a pin of the fastening element, as required by claims 27 and 49 of the present application. The hole pattern of structure 73 of Vincent et al. is triangular, while there is no triangular pin in Vincent et al.

Applicant respectfully submits that new claims 57-70 are also patentable over Vincent et al. Vincent et al. fail to disclose a fastening element for a hip prosthesis having a substantially plate-shaped supporting element having a pin extending from a first side and a coupling element extending from a second side as required by claims 59 and 67. Vincent instead has a bulky block-like supporting member (4) having multiple surfaces (10, 11) in contact with cut portions of bone. This arrangement necessitates a larger amount of bone be removed prior to attachment of the fastening element, making subsequent prosthetic surgeries more difficult. See page 1, lines 16-23 of the instant application. Vincent also fails to disclose cementing the fastening element into place in the bone as required by claim 67, instead using a multitude of screws (20, 23).

As Vincent et al. do not disclose each and every limitation of claims 27, 28, 49 and 50 of the present application, Applicant requests that the rejection of those claims under 35 U.S.C.

§ 102(b) be withdrawn and that the claims be allowed over Vincent et al., and further that the new claims be allowed over Vincent et al.

V. **The Claims Are Novel Over Masini**

Claims 51-56 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Masini, U.S. 5,571,203. Applicant respectfully traverses this rejection.

Masini fails to disclose every element of claims 51-56 of the present application as presented herein. In particular, Masini fails to disclose a pin driven into a bone at an angle with respect to said surface of between about 125° and about 145°. Such permits a much smaller portion of the bone to be removed, as the supporting element need not reside over the longitudinal axis of the bone. This angle corresponds to the neck angle of the original bone. See page 7, lines 10-21 of the present application. The pin of Masini, as can be seen in Figures 2-6, extends at an angle significantly different than that of the neck. As Masini fails to disclose each element of claim 51, from which claims 52-55 depend, Masini likewise fails to anticipate claims 52-55.

Masini likewise fails to disclose each element of claim 56, which depends from claim 34. Initially, as claim 34 has not been rejected over Masini, the Examiner has implicitly acknowledged that Masini fails to disclose each element of claim 56. Further, as claim 34 requires the pin have a longitudinal axis that extends at an angle of between about 125° and about 145° with respect to the bottom surface of the supporting element, Masini fails to anticipate claim 56 for the reasons just stated with respect to claims 51-55.

New claims 57 and 58 are likewise novel over Masini. The coupling element of Masini can be seen from Figures 2-6 to extend from a point directly over the longitudinal axis of the bone. Thus, claims 57 and 58 are novel over Masini.

New claims 57-70 are patentable over by Masini, because Masini fails to disclose a fastening element for hip prosthesis having a coupling element extending from a second side of the supporting element and offset with respect to the longitudinal axis of the pin as required by claims 59 and 67. Instead, Masini discloses a coupling element that extends from the supporting element 226 in line with the longitudinal axis of the Masini pin (312). To the extent that anchoring rod 250 is considered the pin, Masini fails to disclose a pin that is rotationally asymmetrical in cross-section, taken at right angles to the longitudinal axis of the pin, as required by claims 59 and 67. As such, Masini fails to anticipate the subject claims.

Masini also fails to disclose a fastening element for an implant with a pin having a longitudinal axis extending at an angle of between about 125° and about 145° with respect to the bottom surface of the supporting element as required by claim 64 and 69. Similarly, Masini does not disclose a pin having a longitudinal axis extending at an angle greater than about 145° as required by claims 66 and 71. Pin 312 of Masini, as can be seen in Figures 2-6, extends at a 90° angle from the supporting element 226. For this separate and additional reason, claims 64, 66, 69 and 71 are novel over Masini.

As Masini does not disclose each and every limitation of claims 51-57 of the present application, Applicant requests that the rejection of those claims under 35 U.S.C. § 102(b) be withdrawn and that the claims be allowed over Masini, and further that the new claims be allowed over Masini.

## **VI. The Claims Are Non-Obvious Over Yapp**

Claims 4, 5, 7-9, 12, 15, 37, 40-42, 45 and 48 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Yapp. Applicant respectfully traverses this rejection.

Yapp, as noted above, fails to disclose each and every element of claim 1, from which claims 4, 5, 7-9, 12, and 15 depend. Namely, Yapp fails to disclose a fastening element for an implant having an at least largely hollow pin having an inside bone contact surface and an outside bone contact surface as required by claim 1. Because Yapp lacks this element of the claim, Yapp, standing alone, cannot be used to establish a *prima facie* case of obviousness. To do so, the reference must teach or suggest all of the claim limitations. MPEP 2142.

Yapp, as noted above, also fails to disclose each and every element of claim 34, from which claims 37, 40-42, 45 and 48, and therefore likewise be used, standing alone, to establish a *prima facie* case of obviousness.

Yapp likewise fails to disclose each and every element of the new claims, and thus cannot establish a *prima facie* case of obviousness standing alone.

As Yapp does not teach or suggest each and every limitation of claims 4, 5, 7-9, 12, 15, 37, 40-42, 45 and 48 of the present application, Applicant requests that the rejection of those claims under 35 U.S.C. § 103(a) be withdrawn and that the claims be allowed over Yapp, and further that the new claims be allowed over Yapp.

## **VI. The Claims Are Non-Obvious Over Yapp in View of Grimes**

Claims 6 and 39 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Yapp in view of Grimes, U.S. 4,795,473. Applicant respectfully traverses this rejection.

Yapp, as noted above, fails to disclose each and every element of claim 1, from which claims 4, 5, 7-9, 12, and 15 depend. Namely, Yapp fails to disclose a fastening element for an implant having an at least largely hollow pin having an inside bone contact surface and an outside bone contact surface as required by claim 1. Nothing in Grimes remedies this deficiency in Yapp. Grimes instead has a solid stem 27 extending from the collar 27; see Figure 1 of Grimes. Because both Yapp and Grimes lack this element of the claim, the combination of Yapp and Grimes cannot be used to establish a *prima facie* case of obviousness. To do so, the combined references must teach or suggest all of the claim limitations. MPEP 2142.

Yapp likewise fails to disclose a fastening element for an implant with a pin having a longitudinal axis extending at an angle of between about 125° and about 145° with respect to the bottom surface of the supporting element as required by claim 34, from which claim 39 depends. Grimes also does not remedy this defect. The stem of Grimes can be seen to extend at approximately a right angle from the collar 27; see Figure 1 of Grimes. Therefore, the combination of Yapp and Grimes cannot be used to establish a *prima facie* case of obviousness.

As an additional reason in favor of the patentability of claims 6 and 39, Grimes fails to teach or suggest a coupling element that is offset with respect to the longitudinal axis of the pin, as required by claims 6 and 39. Grimes instead teaches a neck 29 whose central longitudinal axis AX-4 is skewed with respect to the longitudinal axis AX-1 of the solid stem 27. The Grimes neck is not offset, as can be seen in Figure 1 of Grimes, because the centerline of the neck extends from the centerline of the stem. Yapp, as acknowledged by the Examiner, does not teach or suggest such an offset. Thus, for this additional reason, the combination of Yapp and Grimes fails to render claims 6 and 39 obvious.

New claims 57-70 are also non-obvious over Yapp in view of Grimes. Yapp, as noted above, fails to disclose each and every element of claims 59 and 67, from which the remaining claims depend. Namely, Yapp fails to disclose a fastening element for hip prosthesis having a coupling element extending from a second side of the supporting element and offset with respect to the longitudinal axis of the pin as required by claims 59 and 67. Nothing in Grimes remedies this deficiency in Yapp. Grimes instead teaches a neck 29 whose central longitudinal axis AX-4 is skewed with respect to the longitudinal axis AX-1 of the solid stem 27. The Grimes neck is not at an offset, as can be seen in Figure 1 of Grimes, because the centerline of the neck extends from the centerline of the stem. In other words, the coupling element of Grimes is also not at an offset with respect to the longitudinal axis of the pin; see Figure 1 of Grimes. Because both Yapp and Grimes lack this element of the claim, the combination of Yapp and Grimes cannot be used to establish a *prima facie* case of obviousness.

Grimes likewise fails to remedy the deficiency of Yapp in not disclosing cementing the fastening element into place in the bone as required by claim 67. Grimes instead uses a complex set of plates 13 and screws 23, along with set screw 41, to attach its fastening element. Finally, Grimes fails to disclose a fastening element for an implant with a pin having a longitudinal axis extending at an angle of between about 125° and about 145° with respect to the bottom surface of the supporting element. Grimes also does not remedy this defect. The stem of Grimes can be seen to extend at approximately a right angle from the collar 27; see Figure 1 of Grimes. Therefore, the combination of Yapp and Grimes cannot be used to establish a *prima facie* case of obviousness.

As the combination of Yapp and Grimes does not teach or suggest each and every limitation of claims 6 and 39 of the present application, Applicant requests that the rejection of

those claims under 35 U.S.C. § 103(a) be withdrawn and that the claims be allowed over Yapp and Grimes, and further that the new claims be allowed over Yapp in view of Grimes.

**VI. The Claims Are Non-Obvious Over Masini in View of Tager et al.**

Claims 29-33 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Masini in view of Tager et al., U.S. 5,330,536. Applicant respectfully traverses this rejection.

Masini fails to teach or suggest each and every element of claim 29, from which claims 30-33 depend. In particular, Masini fails to teach or suggest driving a substantially hollow pin into a bone such that an inside surface and an outside surface of the hollow pin contacts bone. Tager et al. fail to remedy this deficiency. The hollow portion of Tager et al. would not serve as the pin of Masini as there is no means to extend a rod through the hollow portion of Tager et al and extend it to anchor to the lateral outer cortex of the bone shaft, as required by Masini at column 2, lines 6-12. Further, such anchoring must establish a pivot point between the rod and the flange of Masini. See column 2, lines 10-18, describing the pivoting action made possible by this arrangement as being of importance in the distribution of forces in the Masini implant.

Additionally, to establish a prima facie case of obviousness, the Examiner must show some motivation to combine the references. Here, there is no such motivation. The rod of Masini (250 in Figure 2 of Masini) need not have ingrowth of bone, as it does not serve an antirotational purpose. In other words, so long as the rod of Masini remains firmly against the lateral outer cortex (e.g. at 235 of Figure 2) and firmly against the flange (e.g. at 234 of Figure 2), there is no requirement that there be bone ingrowth into the rod of Masini. Masini has separate antirotational devices (for example, 312 of Figure 3) that bone ingrowth locks into

place. There is no reason that one of skill in the art would modify the teachings of Masini with those of Tager et al. Thus, a *prima facie* case of obviousness is not established.

The combination of these references also fails to teach or suggest the limitations of claims 30-33, which depend from claim 29. For example, neither reference teaches or suggests the pin being driven into the bone at an angle such that the longitudinal axis of the pin extends approximately parallel to the longitudinal axis of the neck, as required by claim 31.

New claims 57-70 are patentable over Masini in view of Tager et al. As noted above, Masini fails to disclose a fastening element for hip prosthesis having a coupling element extending from a second side of the supporting element and offset with respect to the longitudinal axis of the pin as required by claims 59 and 67. Tager et al. fail to remedy this deficiency. The coupling element 14 of Tager et al. extends from the longitudinal axis of the pin 10, at least as to the portion of the pin immediately adjacent the collar 12, and could not reasonably be described as being at an offset from that axis.

Additionally, as noted, there is no motivation to combine these references. Thus, a *prima facie* case of obviousness is not established.

As the combination of Masini and Tager et al. does not teach or suggest each and every limitation of claims 29-33 of the present application, Applicant requests that the rejection of those claims under 35 U.S.C. § 103(a) be withdrawn and further that the new claims be allowed over Masini and Tager et al.

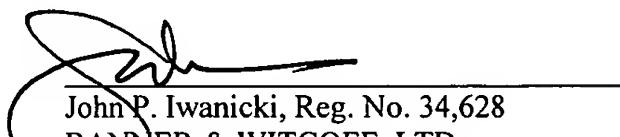
V. **CONCLUSION**

Reconsideration and allowance of all the pending claims is respectfully requested. If a telephone conversation with Applicant's attorney would expedite prosecution of the above-identified application, the Examiner is urged to call the undersigned at (617) 720-9600.

The Commissioner is hereby authorized to charge any additional fees or credit overpayment to Deposit Account No. 19-0733.

Respectfully submitted,

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